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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,794	03/23/2001	Robert S. Lowe	20276P	1127
210	7590	11/17/2004	EXAMINER	
MERCK AND CO INC P O BOX 2000 RAHWAY, NJ 070650907			GUZO, DAVID	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,794

Applicant(s)

LOWE ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 10 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/9/01; 10/15/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 9/13/03
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Detailed Action

The indicated allowability of claims 1-4, 9 and 12 is withdrawn in view of the newly discovered reference(s) to Gissmann et al. and in view of newly applied rejections under 35 USC 112, 2nd paragraph. Rejections based on the newly cited reference(s) follow:

Sequences

The Sequence Listing filed 10/23/03 has been entered. However, the application is not in compliance with the Sequence Rules because the response filed 10/23/03 failed to include an amendment directing entry of the paper copy of the Sequence Listing into the specification. Any response to this Office Action which does not include complete compliance with the Sequence Rules will be considered non-responsive.

35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissmann et al.

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Applicants claim a method of delivering a peptide or protein to a cell comprising:

a) fusing a 1st nucleic acid encoding the peptide or protein to a second nucleic acid encoding a modified human papillomavirus (HPV) L2 to create a fusion protein gene, wherein the L2 portion of the fusion protein gene is less than a full-length L2 gene, but encodes domains from the amino and the carboxyl termini; b) expressing the fusion protein gene in a host cell to obtain fusion protein; c) contacting the fusion protein with HPV L1 protein under conditions wherein the fusion protein and the L1 protein spontaneously combine to form a virus-like particle (VLP); d) delivering the VLP to the cell. The HPV can be selected from HPV11, HPV16, HPV18, etc. and the L2 fusion protein can be a fusion with a E1-E7 sequence. Applicants also claim a nucleic acid encoding a fusion peptide or protein comprising: a first segment comprising a nucleic acid encoding a portion of an HPV L2 protein which is less than a full-length sequence, and a second segment comprising a nucleic acid encoding a peptide or protein.

Gissmann et al. (US 6,066,324, issued 5/23/00, effective filing date 10/2/97, see whole document, particularly the Abstract, Column 3, lines 44-67; Column 4, lines 7-55; Column 6, lines 8-26; Column 7, lines 23-37; Column 8, lines 19-37) recites a method of delivering a peptide or protein to a cell comprising: a) fusing a 1st nucleic acid encoding the peptide or protein to a second nucleic acid encoding a modified human papillomavirus (HPV) L2 to create a fusion protein gene, wherein the L2 portion of the fusion protein gene is less than a full-length L2 gene, but encodes domains from the amino and the carboxyl termini; b) expressing the fusion protein gene in a host cell to obtain fusion protein; c) contacting the fusion protein with HPV L1 protein under

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conditions wherein the fusion protein and the L1 protein spontaneously combine to form a virus-like particle (VLP); d) delivering the VLP to the cell. The HPV can be selected from HPV11, HPV16, HPV18, etc. and the L2 fusion protein can be a fusion with a E1-E7 sequence. Applicants also claim a nucleic acid encoding a fusion peptide or protein comprising: a first segment comprising a nucleic acid encoding a portion of an HPV L2 protein which is less than a full-length sequence, and a second segment comprising a nucleic acid encoding a peptide or protein. It is noted that Gissmann et al. teaches that the foreign protein can be inserted in a deleted portion which is in the middle of the L2 protein and therefore it must be considered that the L2 protein still encodes a amino and carboxyl terminal domain(s). Gissmann et al. therefore teaches the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al.

Applicants' invention is as described in the above 35 USC 102(e) rejection.

Gissmann et al. (WO 96/11272, published 4/18/96, see whole document, particularly pages 7-9, 12-13 and 15-17) teaches the same embodiments as the Gissmann et al. patent (6,066,324). It is noted that the disclosure of the WO 96/11272 document appears to be identical to the disclosure of the 6,066,324 patent. However,

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since the WO 96/11272 document is in German, the examiner will have a translation prepared. Gissmann et al. therefore teaches the instant invention.

35 USC 112, 2nd Paragraph Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 (and dependent claims) are vague in that it refers to "the HPV" of Claim 1. Claim 1 recites two HPVs in the context of a HPV L2 encoding nucleic acid and a HPV L1 encoding nucleic acid. It is unclear what HPV is being referred to in claim 2.

Claim 3 is vague in that there is no antecedent basis for the term "the L2 gene" in the claims from claim 3 depends.

Claim 9 (and dependent claims) are vague in that it refers to "the HPV" of Claim 8. Claim 8 recites three HPVs in the context of a HPV virus like particle, a HPV L2 encoding nucleic acid and a HPV L1 encoding nucleic acid. It is unclear what HPV is being referred to in claim 9.

Any rejections not repeated in this Office Action are withdrawn.

Claims 8 and 10 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo Ph.D., whose telephone number is (571)


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272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
November 15, 2004


DAVID GUZO
PRIMARY EXAMINER